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CHAPTER THREE

The Roles of Values and Interests in the Governance of the Life Sciences: Learning

Lessons from the ‘Ethics+’ Approach of UK Biobank

Graeme Laurie, Ann Bruce and Catherine Lyall

Introduction

In this chapter we explore whether the different instruments of governance provide appropriate methods for negotiating between different value-positions and balancing different interests of various stakeholders. We argue that each of the instruments of governance – whether these involve a key role for scientific evidence, stakeholder engagement, ethical oversight or other means – can contribute to varying degrees in these processes but none is perfect in this respect. We contend, however, that a crucial element in improving the relationship between governance models and the stakeholders affected by them is the incorporation of mechanisms that make explicit the value-positions that inform and are supported by decisions or policies, and the articulation of reasons for these decisions or policies as they impact on governance of the life sciences. The objective should not be to attempt to reflect most values nor necessarily to accommodate the majority of interests, but rather to develop models of *reflexive* governance, that is, models which are democratic and systematic in garnering evidence about the range of values and interests at

stake, in exploring where (and why) there are commonalities and differences, and in developing policies or taking decisions which are ultimately acceptable to a body of ‘reasonable’ stakeholders. Above all, these models of governance must be *responsive* to change as the life sciences, their associated technologies, societal values and stakeholders’ interests evolve through time.

This entire volume is concerned with new models of governance, and in this chapter we examine one example of experimental governance that exists in the life sciences today: the case of UK Biobank.¹ We characterise this as an ‘Ethics+’ approach, by which we mean that its governance regime has been developed *over and above* existing regulation and governance mechanisms, for reasons that we explore presently, and in ways that have not previously been tried or tested. This example serves as an interesting illustration, of how models of governance might be revisioned into a more reflexive mode in order to meet the current and future challenges of the life sciences.

The chapter proceeds as follows. We first outline the government-governance distinction, characterised elsewhere in this book, and give reasons for considering the values-interests dimension as important in this context. We then explore the history, nature and workings of the UK Biobank governance model and set it within a framework which examines how values and interests are likely to come into play in the context of the project.

¹ We should, at this stage, declare a particular interest, which is that one of us, Graeme Laurie, is currently Chair of the UK Biobank Ethics and Governance Council – a key element of the novel governance framework (as we discuss below). That said, Laurie writes here in an entirely personal, academic capacity and nothing herein should be taken to reflect the views of the Council.

This framework contains some of the key elements of governance, such as the role of scientific evidence, trust, choice, public engagement, and ethical/oversight committees. We analyse throughout how the particular governance arrangements of UK Biobank do or do not reflect our aspirations for *reflexive governance*. Finally, we consider whether, and how, it may be possible to ‘future-proof’ governance arrangements, both in the context of UK Biobank and beyond.

Government and Governance

A series of controversies in the UK in the 1990s, including BSE, *Salmonella* in eggs, Foot and Mouth Disease and the prospect of genetically modified (GM) food, undermined public confidence in the ability of science to provide adequate and trustworthy evidence for decisions about trajectories in the life sciences and led to the questioning of the role of scientific evidence in decision-making and policy formation.

At the same time, the development of new governance structures, for example under the *Modernising Government* agenda (HM Government 1999), sought to refashion the processes of governing, including a framework for excellence in policy-making and a strong emphasis on inclusivity and learning lessons from policy experience in other countries. This led to a heightened focus on an ‘evidence-based’ approach to policy-making - with a philosophy of ‘what matters is what works’ (Solesbury 2001); and an emphasis on the need for collaboration (to identify what matters) and the role of ‘evidence’ (to discover what works) (Nutley and Webb 2000).

The governance perspective therefore emphasises the co-ordination of multiple actors and institutions to define and achieve goals in a complex political arena where the hierarchy steers the policy-making process with a lighter touch than may previously have been the

case: hence a ‘new mode of governance’ (Lyall et al. Chapter 1 this volume; Lyall and Tait 2005) has emerged which focuses on participatory approaches and institutionalised co-ordination between the supra-national, national and regional levels. This is leading to increasingly complex state/society relationships where networks rather than hierarchies dominate the policy-making process and there is a blurring of public/private boundaries (Bache 2003). As discussed in Chapter 1, many of the complicating factors identified in the application of the governance agenda to science and technology-related issues arise from complex interactions between the still-necessary, government-based regulation and control of technology and the main themes of the governance agenda, particularly the contrasting and sometimes incompatible requirements for policy decisions to be evidence-based and at the same time for a greater degree of stakeholder engagement in decision-making.

‘What works’ may not be a question of facts or evidence, so much as an understanding of context and an articulation and clarification of values; this requires a decision-making process that is open and democratic and which can facilitate a process of ‘deliberation and public learning rather than (strategic) control’ (Parsons 2001). This, in turn, raises concerns about transparency and accountability, and has led to calls for - and questions about - the representativeness of those included in deliberations (Newman 2001, 68). It implies an iterative process and not the imposition of an inflexible and unresponsive system of command. The process is made all the more complex by the fact that decisions are more likely to emerge or accrete over a period of time (Nutley and Webb 2000).

The context, then, for the need for governance was the perceived necessity for inputs other than scientific evidence in order to ensure that a specific technological development met public and stakeholder expectations and demands to avoid, as far as possible, damaging

conflict situations. The challenges of this ‘new governance’ of science and technology lie less in the philosophy of the approach but more in its execution. It is this execution in a practical example that we will examine in this chapter.

The example to be used is the ‘Ethics+’ approach to governance that applies to UK Biobank. Before examining our case study in detail, however, it is important to add a further layer of analysis to the approach adopted in this chapter and which complements the contributions found elsewhere in this volume. This is the particular role played by interests and values within the rubric of new governance regimes; that is, we seek to explore how, how well, and how far (different) interests and values are built into the architecture and operation of new models of governance. Our premise is that this is a potentially invaluable approach to examining governance design. We contend that emerging models of governance need to be able to negotiate different value-positions and interests if these regimes are to realise their objectives as effective and efficient means to promote the stakeholder agenda within the life sciences in the twenty-first century.

Interest-based and Value-based Positioning

Potential and actual conflicts around science and technology arise from a complex interaction of ethical and social issues; of concerns about risk and its management; of questions of power and control; of varying value-assumptions and preferences; and of contrasting and diverging interests in a given science or technology project or trajectory.

The need to ascertain the root causes of a dispute has long been a basic tenet of mediation in conflict situations (e.g. Burton 1990). Distinguishing between interests and values, and identifying the consequent differences in types of possible resolution to conflicts that invoke interests and values, has also been important in the mediation tradition

(Burton 1990). Miscommunication in a dispute may arise when one party considers an issue as an interest and the other considers the same issue to be a non-negotiable value. However, once a fundamental value is articulated and recognised, it may be possible to negotiate means of satisfying this which are acceptable to others who do not share the same value. By contrast, a range of interests may well be readily accommodated, not all of which will be congruent, assuming that these are not in direct conflict with each other. But failure to recognise the different nature of value-based and interest-based arguments may mean that the root of a dispute and the factors that are really important to protagonists are not uncovered. Attempts at resolution may, then, be entirely fruitless because they miss the point about what is actually, and fundamentally, at stake. Tait (2001) gives an example of this in the context of regulation of genetically modified (GM) crops where the risk regulatory regime tasked with regulating GM crops had no mechanism for dealing with objections such as the appropriate level of corporate control over food chains or preferences over the type of food production system (intensive vs organic).

Most disputes are, of course, an amalgam of value-based and interest-based arguments raised within a particular context. Nevertheless, understanding these dynamics may be important in leading to improved solutions for resolving disputes around new technologies or other advances in the life sciences.

Tait (2001) extensively studied the debates around GM crops and developed a conceptual approach that distinguishes between value-based and interest-based arguments surrounding the technology. She exemplifies the conception of interest-based and value-based conflicts as follows: the former is characterised as ‘Not-in-my-backyard’, the latter as ‘Not-in-anybody’s-backyard’. She suggests that the nature of conflicts varies depending on

the extent to which values become involved. Bruce and Tait (2003) observe that values and interests of an individual may be congruent or they may be in opposition. For example, an individual with a degenerative disease who may have an interest in the development of embryonic stem cell therapies may well object to the development of such therapies on the basis of their values. Value-positions pose particular difficulties because they may be hidden and unarticulated for strategic purposes, because they are not deemed acceptable, or because they are so deeply entrenched that they appear to require no articulation as the presumption is that they are commonly-shared and acknowledged. The two types of argument have rather different characteristics. Interest-based conflicts tend to be restricted to specific developments, are likely to be organised locally, and can often be resolved with the provision of (i) more information, (ii) compensation or (iii) compromises through negotiation. Value-based conflicts, in contrast, often represent ‘ideological opposition’ which tend to spread across related developments (e.g. *any* use of human embryos for research purposes), are often organised on a national or international basis, and may be very difficult to resolve because (i) information can be viewed as propaganda, (ii) compensation as bribery, and (iii) negotiation and compromise as betrayal (Bruce and Tait 2003).

It is often assumed that the interests in question are largely, or solely, *self-regarding interests* – if true, then this may be fatal to any accommodation of a plurality of positions in any given technology trajectory. By the same token, if value-based positioning is equated with ideology and the defence of ‘The Cause’ there may equally be no room for accommodation. In such cases promotion of The Interest or The Value becomes the desirable end, nothing more. This leaves but two options: the defeat of one party or the other – the offending industry or the pressure group (to use a clichéd paradigm).

But what lessons can be learned from such a clichéd example? In particular, what might we take from these dynamics that tend towards polar opposites to design better governance regimes that do not tend, inevitably, towards irresolvable conflict?

We can begin by reconsidering the nature of values and interests themselves. It is possible, for example, for interests to be *other-regarding*, such as the interests of other persons or other stakeholders, of future generations, or of the (admittedly amorphous) public interest. Values, too, need not be uni-dimensional nor inevitably determinative of any particular outcome to the exclusion of other options. Secondly, and whether or not partisan positioning has occurred, a proper articulation of the range of values and interests at stake in any given scientific endeavour affords all parties the fullest possible account of factors to be considered. Rather than a means to the end, then, values and interests can serve to inform the governance process and to open up options, both in terms of the possible ends towards which the process could proceed, and in terms of reaching an accommodation of ends, if this is appropriate in the circumstances. By the same token, it should not be thought that this would merely be a crude process to stake out non-negotiables or to identify different tolerances among different stakeholders; it can also serve to explore more deeply what underlies interest and value positions, to offer the holders of those positions an opportunity to engage in and around those positions, and it can generate an environment where there are legitimate expectations that those positions will be taken into account. This is what we mean by a *reflexive* mode of governance.

A proper articulation of values and interests is important precisely because of their fundamentality both to those who hold them and to setting a defensible course for policy, decision-making and action. To have one's position taken into account, however, clearly

cannot mean that all positions will hold equal sway, for reasons which are trite and need no repetition here. It can require, however, that any model and process of governance makes explicit the values and interests that are in play in the model that has been established, those which are not, and the reasons why one or more positions have been preferred over others. Clearly, this should be more than a ‘like-it-or-lump-it’ approach to governance, and we explore the contours of this in more detail below.

For now, we raise a final point for this section which arises from our discussion of a *process* of governance: this reflects the fact that it is important to appreciate that values and interests can, and do, change over time. An effective governance regime must be able to anticipate and respond to these (and other) changes – and thereby to avoid future conflict – and it will only be able to do so if mechanisms are in place to engage with stakeholders throughout the life of the scientific endeavour and thereby to identify, map and respond to any shifting dynamics around their values and interests.

We use the terminology ‘stakeholders’ here to include everyone who has a stake in the development (whether they are aware of this or not). This includes scientists, policy makers, research funders, and - in the context of our case study: participants in UK Biobank, staff of UK Biobank, UK Biobank management and advisory bodies, people running other biobanks, health-care staff and patients, industry, NGOs, and a wide range of publics. There is therefore unlikely to be a single ‘stakeholder’ view that needs to be taken account of but rather a range of values and interests that need to be negotiated. While the terminology of ‘values’ and ‘interests’ oversimplifies particular situations, such a framework for thinking about what is at stake may bring increased appreciation of the position of stakeholders and it can play a key role in uncovering greater sensitivity to

potential conflicts and fuller appreciation of how these can be avoided or more effectively resolved should they ever arise. What, then, are the values and interests at stake with biobanks?

Values and Interests in Biobanks and the Role of Scientific Evidence

We do not intend to enter a discussion of the diverse meanings of the term ‘biobank’ for the purposes of this chapter. We are concerned primarily with exemplars which involve collections of human biological material, together with genotypic and/or phenotypic data from participants, collected on a large-scale and often at a population level, and with a view to establishing a research resource that will persist for an indefinite period of time.

The experiences of early biobanks of this kind, and public reactions to them, have already provided insight in identifying the kinds of values and interests at stake. The Icelandic Health Sector Database attracted considerable criticism, for example, not only for its plans to link genetic, health and genealogical data of the Icelandic people on the basis of presumed consent (that is, on the premise that citizens would be included in the project and that the ‘choice’ was to *opt-out* not to *opt-in*), but also for the decision to grant an exclusive licence to a single company (deCODE genetics) to construct and manage the database (Gertz 2004). On the other hand, the needs of potential users of the resource (scientists and commercial parties) also need attention in order to ensure a successfully-functioning enterprise. A biobank developed in a region of Sweden (Västerbotten County), marketed as an ethical biobank and involving a Swedish biotechnology company (Uman Genomics), folded in part due to disputes over allocation of intellectual property rights and difficulties in matching its ethical oversight model with the intellectual property requirements of an economically-viable venture (e.g. Rose 2003; Hoyer 2004). These examples demonstrate

that there are a range of stakeholders with interests both in the success of a biobanking project, but also its set-up and governance mechanisms; key among these groups are participants and potential users/collaborators.

More fundamentally, however, there are those who question genetic and genomic databases as valuable projects in their own right; this is not because of concern about how far, or how well, various interests are recognised or protected, but because of concerns about the science itself or the merits of spending finite resources in this field of enquiry as opposed to others. In other words, there are also value-based objections to these endeavours.

We suggest, accordingly, that it is helpful to consider more closely the nature of values and interests in biobanks, and the role of scientific evidence in setting the scientific agenda and in decision-making, before examining how these have been addressed within the context of UK Biobank.

Values

One of the main value dimensions involved in biobanks (Bruce and Tait 2004) is the contribution of genetics research to health care in comparison to other health care measures (e.g. public health measures, environmental measures). For some, the balance appears to be too far in the direction of genetics at the expense of the ‘real’ causes, such as diet, lack of exercise and pollution (e.g. GeneWatch UK 2002). The objection is not necessarily to the existence of biobanks *as such*, but to the culture of favouring genetic explanations of illness to environmental ones. UK Biobank, for its part, has a strong emphasis on collecting lifestyle, diet and environmental information unlike some biobanks, therefore this tension is potentially less relevant to UK Biobank than some other initiatives. Notwithstanding, it

must be acknowledged that the very ‘science’ of biobanks can be seen to have become a disputed matter of values, calling into question the role of scientific evidence - which has traditionally been seen as ‘value-neutral’ – in setting agenda and in decision-making.

The current approach to agenda-setting and decision-making in scientific areas has particular features:

- it presupposes separate value-neutral and value-laden stages in the processes;
- it preferences the allegedly value-neutral ‘evidence’ stage and, because of this, is predisposed at further stages towards any value system that follows that evidence (and by implication is less disposed to value systems which question or reject that evidence);
- it perpetuates a fallacy that there is any such thing as a value-neutral position (or evidence).

But scientific debates in the policy realm increasingly take place in a context of uncertainty, and this is particularly true in the context of biobanks. This is so equally because of uncertainty about the science knowledge-base (because it is at the cutting-edge of knowledge and because it is long-term), and because there is evidence of growing mistrust in the sources of the available information, leading to uncertainty about social attitudes and tolerances, which might shift, unpredictably, at indeterminate points in the future. This can have at least two dramatic consequences. First, parties in dispute may conveniently find ‘evidence’ to support their respective positions, each thereby mustering strength and further entrenching their stance. Second, in the absence of reliable or accurate evidence, parties may fall back unquestioningly on their respective (diametrically opposed) interest or value-positions. The net result in both circumstances is often polarisation of debate and policy stalemate.

This is not to denigrate the contribution that sound scientific evidence should have in the evidence-based policy process. Science that is evaluated in its own sphere as being of

good quality should be an essential component - but only one component. From the above it is clear that scientific evidence will be contested once other principles enter the fray. A failure to appreciate this might steer the discourse in a particular direction and away from a free and full discussion of the range of value-positions that might be in play. The reality is that there is often a wide margin of possibilities in how a particular piece of scientific evidence can be interpreted.

Scientific evidence clearly has a key role in providing an evidence-base, but it is one that should allow different options to be elucidated, new futures to be envisaged and new policy options to be developed (Pielke 2007). Furthermore scientific expertise should come from a wide range of relevant disciplines. Expertise of non-scientific actors in the particular policy domain can also provide useful evidence of how science and technology interacts with practice. Wider stakeholder (including public) participation may have particular input in defining how issues are framed and in bringing in a wider set of values, as we discuss further below.

Interests

Some of the interests which underlie the development of genetic databases include (Bruce and Tait 2004):

- the scientific drive to use new knowledge to improve health;
- the need to ensure that people who participate are protected from harm because of information derived from information and biological material donated to biobanks;
- a fair distribution of any benefits materialising from the use of the biobank resource.

We categorise these specific features as ‘interests’ because they are inherently negotiable. However, there will be various values that underpin these interests, such as the

value of increasing scientific knowledge and the value of preventing exploitation and safeguarding a commitment to basic principles of justice. Overarchingly, there is also the value in promoting the public good through such endeavours, although, as we have indicated above, these particular *means* to promote such a common value are themselves disputed matters. Nonetheless, if the value of biobanking is accepted, there remains the question of *how* the public good is to be furthered through the biobank, and here we increasingly find the language of the *public interest* being used. We have, then, a range of interests arising from biobanks, with a corresponding range of potentially conflicting interest-based positions. The logically-prior question is, however, *how* are these interests to be recognised, negotiated, respected and protected (or otherwise).

We suggest that there has been a net failure to date to address this question to any meaningful extent in the context of biobank governance mechanisms. Indeed, this is symptomatic of failings that we have identified in other areas of the life sciences which nonetheless purport to adopt approaches that are more oriented towards stakeholder interests, public engagement and/or participatory democracy. We propose, rather, to consider how a more explicit commitment to exploring values and interests within governance mechanisms can both begin to answer the above question and potentially also to avoid some of the pitfalls associated with other ‘engagement’ strategies.

We now intend to develop this rather abstract discussion by applying it to our case study of UK Biobank. We do so through an examination of UK Biobank’s innovative governance design which deploys a variety of tools and mechanisms to execute good governance and in an attempt to foster trust, including the establishment of an Ethics and Governance Framework, the adoption of a multi-faceted model of broad consent,

commitments to public engagement in decision-making and project development, and on-going oversight from an independent Ethics and Governance Council.

UK Biobank

UK Biobank aims to build a major research resource containing lifestyle, physical and genetic information, as well as samples, from 500,000 people in the UK, aged between 40 and 69. The purpose of UK Biobank is to support a diverse range of health-related research intended to improve the prevention, diagnosis, and treatment of illness, as well as to promote health throughout society, both in the United Kingdom and internationally.

Neither the objective nor the approach of UK Biobank are novel from an epidemiological perspective. The project design, in scientific terms, has been considered and approved by an international scientific review body; and in ethical terms, it has received approval from a multi-centre research ethics committee. Recruitment began in April 2007, and at the time of writing over 160,000 participants had agreed to take part. The recruitment stage will run until 2010, and it is unlikely that access to the resource will be granted before this stage has been completed. UK Biobank is subject to the same plethora of regulations as any other project in the life sciences that involves the participation of human subjects, including the provisions of the Data Protection Act 1998 (with respect to the processing of personal data from which individuals are identifiable), common law duties of confidentiality (again, with respect to the protection of individual privacy), and more recent regulations concerning the storage and use of human materials (under the Human Tissue Act 2004). When the time comes to grant access to the resource, UK Biobank will likely use standard means to control access and use of data or samples from the resource, including data control contracts, material transfer agreements and

intellectual property rights. In all of these respects, then, there is nothing *novel* about UK Biobank. Indeed, there is much in the way of *government* regulatory control already in existence, imposing a top-down, legally-binding framework within which UK Biobank has been developed.

Our interest in the project for the purposes of this chapter, however, arises from its entirely novel approach to *governance*, and its potential impact on the life sciences policy arena. The actors involved in this area are not directly policy makers although the expected provision of information arising from the UK Biobank resource is expected to have considerable policy relevance and fits in well with the policy aim of realising the potential of genetic information as set out by the UK Department of Health:

Our genes play a fundamental role in determining our health and our response to healthcare. Six out of ten people are likely to develop a disease that is at least partially genetically determined by the age of 60. Greater knowledge of genetics will have a major impact on our understanding of human illnesses and herald a step-change in disease prevention, diagnosis and treatment. Department of Health 2003, p. 7.

UK Biobank is not, however, a government initiative (at least not strictly nor directly so). Although the Department of Health is involved, the project's main funders are the Wellcome Trust (WT) and the Medical Research Council (MRC).² And, while the MRC is a publicly-funded organisation, the Wellcome Trust is an independent charity and the largest source of non-governmental funds for biomedical research in the United Kingdom. It was upon the initiative of these two funders that the idea to explore the need for an

² UK Biobank is funded by the Wellcome Trust, the Medical Research Council, the Northwest Regional Development Agency, the Department of Health, the Scottish Government and the Welsh Assembly Government.

additional layer of governance was raised when the entire notion of establishing a UK biobanking resource was first mooted towards the end of the twentieth century.

The first initiative in the process of revisioning governance was the establishment of an Interim Advisory Group by the funders to advise on how the project should be established and taken forward.³ A particular challenge for this group was the expectation that it should conduct its deliberations in-parallel with development of the scientific protocol and in light of the scientific evidence arising therefrom. The group met numerous times during 2003-2004 and was able to draw on public consultations conducted before and during this time about the biobanking initiative and its potential governance structures. The core recommendations of the Group were, first, that UK Biobank should adopt an Ethics and Governance Framework which lays out explicitly the commitments of UK Biobank to its participants, the public and other stakeholders, and, second, that a permanent and independent Ethics and Governance Council should be established to oversee the project and to monitor and advise on its operation.

These recommendations were put out to public consultation and ultimately accepted by the funders. The Ethics and Governance Framework is an instrument of UK Biobank and available on its website.⁴ It is designed as a living document to be revised as necessary over time as the project develops, as new and unforeseen challenges arise, and/or

³ The membership of the Interim Advisory Group was: Dr William Lowrance (Chair), Professor Alastair Campbell, Professor Erica Haimes, Dr Graeme Laurie, Professor Chris Mathew, Professor Jean McHale, Mrs Helen Millar, The Baroness O'Neill of Bengarve, and Mrs Madeleine Wang.

⁴ www.ukbiobank.ac.uk

importantly, as social attitudes shift (including values and interests). The Ethics and Governance Council began its work in November 2004 and exists as an entity independent of UK Biobank (albeit funded by the Wellcome Trust and MRC).⁵ We reiterate, however, that these arrangements have been added on top of existing - and what some might consider already-burdensome - layers of control. Why, then, is any other *governance* measure required?

There is no single answer to this question. It is not because of anything unique about the science per se, as we have already suggested, although the sheer scale of the project – to recruit almost 1 per cent of the UK population – has certainly been mooted as a factor requiring special attention to its governance. Second, the long-term nature of the project and the as-yet unknown categories of research which may be conducted with the resource has raised ethical issues about the role of participants’ consent – can this be meaningful when so much about the future is uncertain? Is it acceptable to ask for ‘broad consent *to participate* in UK Biobank’? This also poses related questions about the on-going security of participants’ samples and data once access is granted, and it further raises the issue of monitoring whether UK Biobank will be managed within its broad purposes and true to the original consent given by participants. Paradoxically, despite the range of regulatory practices and bodies that populate the life sciences arena, and notably the role of research ethics committees, there are no bodies with a responsibility for *on-going* monitoring and review of such issues. It was therefore perhaps serendipitous and appropriate that the consultation exercises commissioned by the funders found strong support for the

⁵ www.egcukbiobank.org.uk

establishment of an oversight body to advise on and monitor the management and operation of the project through time.

These factors may help to explain why UK Biobank has been set up in the way that it has, but they do not provide any indication – and certainly cannot guarantee – that it will work as a governance framework. That remains, for now, an unknowable unknown. We suggest, however, that there are two particular features of this mode of governance which should be monitored closely for their role in the success, or otherwise, of this enterprise. These are the Ethics and Governance Framework and the Ethics and Governance Council. Our particular interest in these instruments of governance stems from the fact that they are designed to engage explicitly with values and interests, and from there with participants, other stakeholders and the public at large.

Values and Interests in UK Biobank

UK Biobank is set up as a not-for-profit company. The organisational arrangements for UK Biobank consist of:

- a Board of Directors, with representatives of the funders;
- a Steering Committee, led by a Chief Executive Officer;
- an Ethics and Governance Council, appointed by an open process in keeping the Nolan Principles;
- an International Scientific Advisory Board that meets three times per year.

UK Biobank Ethics and Governance Framework

At the heart of UK Biobank is the Ethics and Governance Framework (EGF) which outlines the commitments to participants, researchers and society at large, as well as the practices to be adopted in the establishment and management of the UK Biobank resource. The purpose of UK Biobank is articulated in the EGF and this is to build a resource to encourage and

facilitate health-related research. The EGF explicitly states that: ‘UK Biobank will serve as the steward of the resource, maintaining and building it for the public good in accordance with its purpose’. With respect to the various interests and stakeholders involved, the EGF deals with each in turn. Thus, concerning participants, the instrument lays out in Section I the details of recruitment, the nature of the consent that will be sought, associated guarantees, and the importance attached to protecting participant confidentiality. Section II deals with the relationship with researcher users, focusing in particular on the role of UK Biobank as steward of the data and samples, and detailing the defining principles of the access policy and expectations surrounding the sharing of results obtained through use of the resource. Finally, Section III explores the relationship with society, and articulates matters of *internal* governance (the roles and responsibilities of the Board of Directors, the Ethics and Governance Council, the Steering Committee and the International Scientific Advisory Board), *external* governance (the need for approval by relevant ethics committees and compliance with the regulatory regimes), and *benefit sharing* (being a commitment to disseminate knowledge generally and an account of policies to use intellectual property judiciously and to reinvest any profit back into the resource).

From a values perspective, the commitment is to manage the resource for the public good, in keeping with the purposes outlined in the EGF, and while honouring the original consent provided by participants (we say more about the nature of this consent from a values-perspective below). From an interests perspective, the EGF is explicit in identifying both the range of stakeholders and the interests considered to be at stake, but it is important to reiterate, once again, that the EGF is a living instrument designed to evolve with circumstances surrounding the project, and most especially the interests of its stakeholders.

UK Biobank Ethics and Governance Council

The Ethics and Governance Council (EGC) has been established to:

- act as an independent guardian of the UK Biobank Ethics and Governance Framework and advise on its revision;
- monitor and report publicly on the conformity of the UK Biobank project with the Ethics and Governance framework; and
- advise more generally on the interests of research participants and the general public in relation to UK Biobank.

It is the role of the EGC to hold a mirror up to UK Biobank to reflect on its commitments to stakeholders as articulated in the EGF, on an on-going basis and as the project itself develops. The mantra of the EGC is to speak *‘about UK Biobank, not for UK Biobank’*. The EGC meets quarterly, holds regular public meetings, reports annually on its work and on its budget, commissions research, maintains a public profile through its website, seeks to engage actively with participants and other sectors of the public about its work and the UK Biobank project, and is ultimately accountable to the funders and the public with respect to these activities and its role in the innovative ‘Ethics+’ approach to governance.

While the EGC is not in a position to impose any formal sanctions on UK Biobank or its staff, it is in a position to communicate publicly on any transgressions of the EGF, of the values that it embodies, or of any of the interests of stakeholders engaged in the enterprise. In a very real sense, this breathes life into the old adage that ‘information is power’, and the EGC can be seen to serve as a vital communication bridge between UK Biobank and its participants and other stakeholders. This further serves an important policing function of

the relationships that lie at the heart of the EGF. The health and success of these relationships are vital to the success of UK Biobank itself.

Building and maintaining trust

It is axiomatic that UK Biobank depends on people's willingness to participate and to maintain sufficient confidence in the project not to withdraw from the biobank in the future.⁶ It is therefore critical to UK Biobank for participants to continue to trust the management and purposes of the biobank over time.

Trust may be undermined in a number of respects from a values and interests perspective. Most obviously, this will occur if individuals' own self interests are not respected or protected, or if it is considered that vested interests hold sway. But the challenge runs far deeper because disregard for the interests of others might also have an undermining effect, as might a change in the way that the project is run or managed, indicating to participants that the values which once underpinned the project no longer hold true or have been replaced.

Learning lessons from the past, Levitt (2003) notes (p. 27) that in the context of GM crops, a lack of transparency and trust between the players (spilling over from the scandal of BSE) gave rise to suspicion about the possible pursuit of vested interests at the expense of the public interest. This resulted in calls for increased transparency, so that people could see how and why particular decisions were being made. In response to this pressure, several organisations have taken to holding at least some of their meetings in public (e.g. the Food

⁶ The right to withdraw is an absolute right which is given to all participants in the EGF and which can be exercised at any time and for any reason.

Standards Agency). But problems remain. O'Neill (2002) has pointed out that organisations and persons may be worthy of trust but not be trusted. Openness and transparency allied to unrealistic expectations may result in further cynicism and a feeling of 'it's just as I feared' rather than the building up of trust. Transparency might mean that the grosser 'inappropriate influences' are kept in the open domain – but this will not necessarily encourage more trust. Transparency is, moreover, often reduced to an obligation of information giving, but since it is never possible to state that one is in possession of all the facts, an element of mistrust may remain. Whether claims are trusted depends, not on facts or information alone – what we might call 'hard evidence' – but on the kinds of relationship that exist between the parties and, we would submit, the kinds of processes that regulate and respond to dialogue between those parties.

Trust, then, is not merely a matter of transparency but is often the result of a relationship. It is perfectly human to trust those with whom we share common beliefs and values, but it is altogether a different matter to determine how to engender trust among those who may disagree with or oppose our values. Acts of transparency are satisfactory only where relationships are already stable, and where there is little reason to doubt the intentions of another. Transparency is therefore unlikely to be the panacea if there is a 'crisis in trust' (Brown 2002). Moreover, transparency is rarely constructed as an obligation to articulate one's values and to demonstrate how these impact on decision-making processes.⁷ Openness in the basis for decision-making can, however, allow the making

⁷ Far more common is the creation and publication of a register of interests, although this is primarily, if not solely, done to flag any actual or perceived conflicts of interest.

explicit of the basis for balancing pros and cons; benefits and risks; different interests and different value-preferences.

Earle (2004) identified two general theories of how people construct a basis for trust: 1) trust is based on observed objectivity and fairness and perhaps also competence and expertise, 2) trust is based on individual judgement and consciously connected with agreement or disagreement, based on, for example, inferred values and quality of the organisation. Thus, in at least one sense the sharing of values, or indeed the recognition of one's value-stance (and that of others), is an important element in building a relationship of trust.

The importance of articulating and seeking to respect various value-stances in the decision-making processes with respect to scientific and technological developments is crucial. This provides not only a framework in which decisions can be taken cognisant of the range of values in play, but it also allows consistency of decisions over time. Consistency is an important element of any trust relationship. Furthermore, an obligation to express clearly one's value-stance necessitates reflexivity, that is, self-reflection on what exactly it means to hold such a value and where its limits lie. It is in the territory between value positions that effective, reasonable, legitimate and legitimated policy is to be found.

UK Biobank recognises the requirement to earn the trust of participants and a number of governance features are in place to enable openness, to establish trust relationships and to encourage reflexivity in how those relationships are maintained over time. The Ethics and Governance Framework is a clear articulation of the value basis upon which the model of governance was established and of how different ethical principles have been negotiated. The Ethics and Governance Council publishes the minutes of its meetings and these not

only record decisions taken but also attempt to convey the processes of deliberation and reasoning undertaken by the Council. Furthermore, on agreement but acting independently, UK Biobank and the Ethics and Governance Council record and explain advice and actions that have required changes to the Ethics and Governance Framework and/or consent documentation, and a recent example is the revision of the ‘No Further Use’ option linked to the right to withdraw. This required change because of technical features of the UK Biobank data archival system which mean that it is not possible to destroy all data *completely* on withdrawal as was once thought.⁸ Some data must remain for audit and archival purposes, but the nature of the original guarantee to participants – that there will be no further use of their data for the purposes of the resource – has not changed.

This last example is one which demonstrates what we mean by *reflexive* governance. The EGC was able to respond to an eventuality which was not, and could not have been, foreseen when the project was set up and the Ethics and Governance Framework established. As a result of a close examination of the issue and the fundamental values and interests at stake, the EGF and consent documentation have been amended, and – just as importantly – these processes and deliberations have been explained and described.

This also speaks to a further challenge for UK Biobank in maintaining trust, which is to demonstrate that it is managed with integrity and consistent with its principles. The Board and funding bodies have a role in this respect but the addition of the independent Ethics and Governance Council provides a further layer of security. Trust, however, is a

⁸ See UK Biobank: <<http://www.ukbiobank.ac.uk/docs/Nofurtheruse.pdf>>, and Ethics and Governance Council: <<http://www.egcukbiobank.org.uk/recentactivity/index.html>>

fragile thing and the benefits of biobanks are in the future and largely uncertain. The way in which information about the future benefits of UK Biobank are communicated and the types of futures that are projected can potentially have an impact on the trust that is placed in UK Biobank. Will it deliver what was promised? The uncertainty around the developments that may be realised through UK Biobank are to a large extent a source of hope (rather than risk as in some other biotechnological developments such as GM crops). Care is needed, however, not to allow ‘hope’ to spill over into unrealisable ‘hype’.

Providing choice

Another way of incorporating values in processes is to allow individuals to make choices among a range of options. The privileging of choice is an important contemporary example of how different values may be, and are, prioritised in science and technology. *Choice* has become the watchword of consumer demand and the key measure of respect for individuals. Thus choice can become the overriding value under which many, or all, other values are to be subsumed. Moreover, *free* choice, such as the choice whether or not to participate in a biobank project, is seen by many as the only acceptable approach to such projects, and was undoubtedly the value basis upon which many objected to the opt-out approach of the Icelandic Health Sector Database. Prudently, perhaps, UK Biobank adopts an opt-in model. The main benefit of enabling choice as a governance tool is to allow individuals to make their own decisions in ways that reflect their own values and interests. But choice as a governance mechanism brings its own challenges, both practically and from a values and interests perspective.

For one thing, it is by no means a trivial exercise to persuade 500,000 to sign up to a research project, let alone one which will continue for an indeterminate length of time.

Furthermore, while ‘better choice’ is almost universally equated with ‘informed choice’, more information does not always unproblematically facilitate choice. Indeed, in the context of longitudinal projects like UK Biobank, *fully* informed choice is not achievable because there are simply too many uncertainties about the future of the resource, including who will seek access, from where, and for what purposes?

This raises a question from an interests perspective as to whether the interests of individual participants are sufficiently protected; more fundamentally, and from a values perspective, it might make a project such as UK Biobank non-viable if we insist that the only acceptable value-basis for its operation is free, fully-informed consent. But this is not the value-basis upon which UK Biobank has been established. The Ethics and Governance Framework makes it clear that there are future uncertainties and it is not possible to explain all eventualities at the time of recruitment. The invitation is ‘to participate in UK Biobank’ with everything that this entails. The value-basis of UK Biobank is to establish a research resource for *future* health-related research for the benefit of *future* generations. The future-oriented nature of the project has a potential impact on the interests of participants in that they cannot be fully informed at the time of recruitment. In a sense, UK Biobank is asking participants to be *other*-regarding. By the same token, additional safeguards are built into the governance mechanism to protect participants’ own interests, including a commitment from UK Biobank to update participants with information about the project as and when it develops, and the existence of an absolute right to withdraw from the project at any time and for any (or no) reason. Again, from a values and interests point of view this can be seen as serving complementary functions. Clearly individuals can withdraw if they consider that their own interests are at risk or have been compromised, but the right to withdraw might

also serve as a means to signal a value-judgement on the project – an expression of disapproval or a message that the relationship between the project and its stakeholders is no longer working.

Choice, then, can be an important governance tool and one that involves some degree of empowerment of participants as stakeholders. In the UK Biobank context choice and trust are closely allied, in the sense that choice in favour of UK Biobank is a measure of trust in the project. The options that it offers are, however, somewhat limited: the choice to participate (or not); the choice to withdraw (or not). In particular, *choice* does not necessarily give you a *voice*. Withdrawal is the ‘nuclear option’. And, while it may only be a last option, it is certainly not an optimal option if *negotiation* of perspectives is thought to be important and desirable as a means to address and resolve conflict and avoid the ultimate choice to withdraw. By the time such a choice is exercised, it is too late for the process of governance. It may even be seen as a failure of governance. This is why we advocate reflexive governance which must involve mechanisms to measure and gauge participants’ (and public) attitudes and to understand what is informing their choices. This gives governance mechanisms the best chance to respond appropriately and timeously to concerns or conflict, and, perhaps, to pre-empt the exercise of the ultimate choice. To do this effectively, some degree of public and participant engagement is required.

The Role of Public and Participant Engagement

We can find plenty of evidence in the wider international life sciences arena that policy makers clearly believe that wider participation in decision-making processes will create more confidence in the resulting policies and in the institutions that deliver them:

‘The quality, relevance and effectiveness of EU policies depend on ensuring wide participation throughout the policy chain – from conception to implementation’ (Commission of the European Communities 2001, 10).

But in the UK, interaction with stakeholders, including the public, has traditionally been seen as consulting in an *ad hoc* way on each particular issue rather than as an ongoing interaction. There is still a tendency for government departments to equate ‘consultation’ with ‘engagement’ (Lyall 2005) rather than to adopt a genuine commitment to user-involvement that goes beyond merely offering the opportunity to ‘participate in participation’ (de la Mothe 2001, 8). Reflecting a trend we have identified with other governance tools, the discourse of participation has often been about crisis management: a largely predetermined range of remedial or damage-limitation options is presented as a means of resolution (Rayner 2003). The funders of UK Biobank have themselves been criticised for their early approaches to consultation,⁹ although it should be noted that the Ethics and Governance Framework was put out for public comment, and the Ethics and Governance Council has commissioned research on publics’ and participants’ attitudes towards access and commercialisation (see further below).

The advantages of such a participative approach may include (Cameron and Danson 2000):

- increasingly innovative policies and better operational decisions arising from dialogue between organizations with different perspectives on problems;
- increased continuity and consistency in policy and decision-making;

⁹ Tutton, Kaye and Hoeyer (2004) urged funders ‘... to consider the inclusion of representatives of the participants in the EGC and other management bodies as a way of securing public trust and support’.

- high level strategic planning and decision-making through shared agreement.

The participative governance approach advocates an increasing role for non-governmental actors and stakeholders in policy and decision-making, often as a means to mitigate public controversy over new technology developments (Lyll and Tait 2005, 182). Studies of participative exercises have suggested (STAGE 2004) that often the main motivation for sponsors of deliberative processes is the desire to achieve social consensus on a development and retain or regain public trust. From our perspective, the major criticism is that the prevailing model may still be more to do with casting stakeholders and publics as interest groups who must be satisfied (but who may, in reality, be polarised), and reducing policy conflicts by controlling the message rather than communicating with, and listening to, stakeholders and publics. Indeed, the process may overlook the fact that policy-making is about dialogue (Parsons 2001).

A considerable amount of public engagement has taken place during the development of UK Biobank (Levitt 2005). Initially, this was primarily in order to understand what issues are important to potential donors to the biobank and to test out what kind of governance and other arrangements would prove acceptable. Thus, initial consultations were carried out from 2000-2003 and helped to inform the work of the Interim Advisory Group, while its main output – the draft Ethics and Governance Framework – was also put out for public consultation in 2003. Since the launch of the project and the establishment of the Ethics and Governance Council, UK Biobank has employed a Communications Officer and the EGC has held regular public meetings, the results of which – in terms of questions asked, answers given and actions undertaken – are reported publicly in its Annual Reports and on its website. Perhaps most significantly, and as a measure of the independence of the

EGC, it has commissioned research on public attitudes towards UK Biobank's stated access policy and the prospect of commercialisation of research arising from the resource. This was undertaken after a scoping paper (Sumner 2007) identified a gap in the social science literature on these topics and in light of evidence from other studies revealing public concerns about commercialisation (Haddow et al. 2007).

Considering these exercises in governance terms, we can ask: what kind of evidence does public participation provide? Scientists and others may be critical of the contribution of public participation because they may perceive the public as emotional rather than rational and open to manipulation by self-interested opponents (e.g. Cook et al. 2004). We should however also note, after Weber (1968), that 'rationality', can be understood in different ways. The more common concept of 'instrumental rationality' involves weighing up consequences of different actions, as in the case of cost-benefit analysis, for example. In the concept of 'value rationality', by contrast, actions are consistent with a particular 'value' position. As Weber points out, 'value-rational' actions appear to be irrational from the perspective of 'instrumental rationality', and the more strongly a 'value' position becomes held for its own sake rather than because of its consequences, the more irrational this will appear from the perspective of 'instrumental rationality'. Moreover, if all that is observed is the 'irrationality' without an understanding of its underlying cause or reason – that is, of the 'value' informing the position – then it becomes easier to dismiss that position rather than to engage further with it. The process then ceases to function as a dynamic, interactive model. Indeed, the model itself may be set up to bring about just such an eventuality by preferencing one view of rationality over another.

What do the public engagement exercises relating to UK Biobank tell us? We can, of course, answer this at a specific or a general level of abstraction. They tell us, for example, that public awareness of UK Biobank is not terribly high, but that there is evidence of respectably high levels of satisfaction among groups informed about the general governance mechanisms of the project. Equally, it seems that there are no statistically significant differences between attitudes among survey participants in the UK Biobank age range (40-69) and a younger generation (18-30). There is, however, some evidence of higher levels of concern about international applications to use the resource (although we do not know what lies at the root of such concern), and there is also some indication that the prospect of commercialisation continues to be a cause of concern (but again, the root cause remains elusive). We recognise the importance of such engagement exercises for both UK Biobank (in managing the project) and the EGC (in exercising its advisory role). Although, once again, they are limited from a values and interests perspective: they do not tell us if, or when, or how, attitudes might shift, nor where publics' tolerances lie with respect to particular policy or management decisions. They are non-representative snapshots in time; and, while they might be repeatable over time and with diverse groups to minimise this limitation, they may be too crude a mechanism to gauge subtle changes in values and interests. Short of offering representation within UK Biobank,¹⁰ yet other complement mechanisms may be required to fulfil this role.

¹⁰ See Winickoff (2007). We do not have space or time to engage with these arguments, see rather, Hunter (*forthcoming*).

Ethical Committees and Ethical Experts

Ethical committees have come to play a key role in arbitrating some areas of genomic technologies and in particular to act as ‘gate-keepers’ to the technology. These committees have traditionally been used in health care and animal research but are now extending to cover wider areas. Additionally, medical research has historically included a layer of ethical approval, which could be understood as an early form of governance (in that membership of ethical committees includes a wider network of actors) or as an additional form of government (in that failure to satisfy the ethics committee means that the research will not proceed – in this sense, it is a top-down ‘regulatory’ tool). Others, such as the Human Genetics Commission, have a wide strategic remit and an advisory role. Ethical committees might be seen as a way of managing morality (as opposed to managing different risks as is the function of much of government). The establishment of the UK Biobank Ethics and Governance Council represents yet another kind of body - one which is non-governmental and non-regulatory, independent and yet financed by research funders, and with a very particular remit, to advise and monitor one particular science project. It is something of an enigma in governance terms. Its value remains to be proven, but we consider that it potentially has much to contribute as a key element in models of reflexive governance, as we suggest below.

The example of the UK Biobank Ethics and Governance Council takes this kind of governance role many stages forward and hence we have coined the terminology of ‘Ethics+’. For one thing, it has an on-going advisory and monitoring role with respect to the research, helping to ensure that it *remains* ethical. Ethics Committees simply provide up-front, one-off approval. Secondly, and again unlike ethics committees, the dealings of the

Ethics and Governance Council are made public by a variety of routes, including published minutes of its meetings, full accounts of its deliberations, and public engagement activities to inform publics about its role and to gauge attitudes (and possible concerns) about UK Biobank. The EGC also has a responsibility to respond to the input it receives, and does so in its annual reports and through its website, where Frequently Asked Questions about its role and advice appear and these are regularly updated as new questions and queries emerge. Finally, the EGC is committed to making explicit the basis for much of its reasoning and what informs its advisory and monitoring role: for example, it has produced documentation that explores and explains its approach to '*advising in the public interest*', which is central to its remit. This kind of engagement and explanation of process is also central to how we view reflexive governance. Without it, we suggest, the dangers of fragmentation of debate and the stalling of policy and decision-making processes may quickly and easily come to the fore. Processes may be fractured along values and interests lines.

We suggest that a key feature of any system must, however, be a genuine, transparent and consistent commitment to receive value-based and interest-based inputs at all stages and an openness to the possibility that these might change the technology or policy trajectory, as far as this is practicable. We acknowledge, however, that once the direction is clear, it may be too late to change; and, even when it is possible to change things, we do not always know what direction we then wish to take. Notwithstanding, the task is about optimising the process through the fullest possible engagement with interest and value perspectives.

We contend that allowing arguments to be expressed and addressed for what they are – that is, on a value-base or alternative future base approach – could remove some of the heat currently placed on ‘scientific’ evidence. We have indicated above that it is not possible or realistic to attempt to satisfy all positions that may be voiced with respect to any life science initiative – either now or over time; indeed, these will doubtless shift as time and society moves on. We cannot, then, ever expect to *future-proof* governance. We have argued, however, that in the context of UK Biobank a new model of governance has emerged – or is at least emerging – and this is *reflexive governance*. It is typified by ongoing engagement with values and interests, responsive and explicit advice and monitoring, and a commitment to explain why particular policy or decisions have been adopted such that this is, at the very least, understandable to a majority of reasonable persons. In this last regard we refer to the work of Daniels (1985, and Daniels and Sabin 2002) for his approach represents one further means of accommodation in value-based conflicts which helps to avoid possible stalemates. In the context of allocation of scarce health resources, he advocates a fair, deliberative process of setting limits on difficult decisions where it is impossible to satisfy all parties. The process is typified by clear articulation of criteria for decision-making, transparency at every level, and an overall aim to reach decisions which are acceptable to (all) reasonable persons because the reasons (and values) behind them are at least understood, even if they are not agreed with. It has been suggested more recently that this process can and should be complemented by public consultation (Williams-Jones and Burgess 2004). We suggest, in turn, that precisely such an approach is now evident in the governance model applied to UK Biobank, and that much will be learned about governance as a result.

Conclusion

Scientific evidence has been used as a rationalist way of providing a basis for government. However, where powerful technologies are raising fundamental questions about our social fabric and our fundamental values, scientific evidence no longer provides a sufficient basis for government, and government no longer provides a sufficient basis for moulding scientific and technological developments. Different perspectives and alternative conceptions of the future are becoming increasingly important and require incorporation in any decision-making or policy-making process. Disagreements on the basis of differing value perspectives have traditionally been a recipe for stalemate. We suggest that part of the reason for this arises, first, from the prevailing model itself; and second, from a failure to engage more fully with the nature and substance of such perspectives.

We need to be able to recognise the potential for value-based conflict at a much earlier stage in the technology trajectory and to create spaces where these aspects can be explored as the trajectory develops. This implies in essence a governance mode of action, and more particularly a mode of *reflexive governance*. We should take care not to reduce a problem prematurely to a limited set of dimensions established by dominant experts. Time should be taken to explore a range of aspects and to test a range of boundaries to a problem. The first step in engaging with values is the recognition that they exist everywhere, sometimes explicitly, but at other times implicitly. Where values are a key element, we should not ignore them nor force them to be expressed in terms of ‘scientific evidence’ but rather we should find a lexicon for talking about them openly in the same way that we now do about ‘risk’. This does not mean rejecting scientific evidence, but rather it means re-envisioning science as but one, albeit essential, ingredient of the decision-making mix; as

evidence to be enriched by other knowledge from different spheres and leavened by an explicit acknowledgement of the values that exist in society. We must make the implicit, explicit.

Consulting on values does not, of course, inevitably mean that we arrive at a shared value position. Such an assumption would be naïve in the extreme. Sometimes good communication can take place and we discover that there are real value differences with very real consequences. Consultation does not take away the need for political judgements about the future direction to be taken.

We started out by identifying that in a governance model collaboration is needed to identify what matters, evidence to discover what works and ultimately what matters is what works. In our example of UK Biobank, collaboration by various stakeholders (including potential and actual participants) is used to identify what matters. A framework has been developed for the governance of UK Biobank but within it is included reflexivity that will allow amendments to be made when deemed necessary and an approach that makes the value-basis of decisions open and explicit. UK Biobank is still in its formative stages with a primary focus on participants. The robustness of the model when strongly challenged by other stakeholders, such as industry or plans for unexpected research avenues from research scientists has yet to be fully-tested.

UK Biobank and its innovative ‘Ethics+’ approach to governance provides an interesting example of where government and governance approaches have been adopted in practice in a potentially contentious area of the life sciences. UK Biobank has combined ‘hard’ government in terms of protecting the interests of participants as well as ‘soft’ governance taking into account different values and interests and ensuring continuing

participation by members of the public in the biobank and its governance processes. This illustrates the way in which government and governance are not functioning as two poles of a continuum nor as two completely intertwined entities, but as a ‘soft’ wrapping of governance around a ‘hard’ core of government. It is inconceivable that ‘government’ alone would provide a sufficient basis for the establishment of the biobank. It requires the active participation of publics and clinicians and in a modern democracy these cannot be obtained by central government edict. On the other hand the legislative framework has provided a layer of protection to participants without which trust in the biobank would be unlikely to be gained.

UK Biobank has made explicit the value basis on which it plans to function in the form of its Ethics and Governance Framework and to date has explained publicly the reasons for any changes in this framework. The UK Biobank Ethics and Governance Council does the same in its role as advisory and monitoring body. The future success of UK Biobank remains to be seen, but – whatever the outcome – much will be learned from the journey.

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